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Pesticide Fact Sheet Number 93.0
'Bacillus thuringiensis'

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U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division (TS-767C)
401 M Street, SW
Washington, D.C. 20460

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Bacillus thuringiensis,

16. Abstract (Limit: 200 words)

This document contains up-to-date chemical information, including a summary of the Agency's regulatory position and rationale, on a specific pesticide or group of pesticides. A Fact Sheet is issued after one of the the following actions has occurred:

1. Issuance or reissuance of a registration standard,
2. Issuance of each special review document,
3. Registration of a significantly changed use pattern,
4. Registration of a new chemical, or
5. An immediate need for information to resolve controversial issues relating to a specific chemical or use pattern.

17. Document Analysis a. Descriptors

Pesticides, regulations, Chemical Information Fact Sheet, Use Patterns, science findings.

b. Identifiers/Open-Ended Terms

c. COSATI Field/Group

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Office of Pesticides and Toxic Substances
Office of Pesticide Programs (TS-766C)
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EPA

Pesticide Fact Sheet

Name of Chemical: Bacillus thuringiensis
Reason for Issuance: Registration Standard
Date Issued: December 1988
Fact Sheet Number: 93.0

1. DESCRIPTION OF THE MICROBIAL PESTICIDE

Generic Name: Bacillus thuringiensis

Common Name: Bt

Trade and Other Names

Trade names for Bacillus thuringiensis subspecies kurstaki include: Dipel, Thuricide, Bactospeine, Leptox, Novobac, Bug Time, Cekubacillina, Attack, Foray, and Javelin.

Trade names for Bacillus thuringiensis subspecies israelensis include: Bactimos, Teknar, and Vectobac.

The trade name for Bacillus thuringiensis subspecies aizawai is Certan.

The trade name for Bacillus thuringiensis subspecies san diego is M-One.

The trade name for Bacillus thuringiensis subspecies tenebrionis is Trident.

EPA Shaughnessy Codes
(OPP Chemical Codes)

Microbial Pesticide Name: Bacillus thuringiensis (all
OPP Chemical Code: 006401 subspecies)

Microbial Pesticide Name: Bacillus thuringiensis subsp.
OPP Chemical Code: 006401 israelensis

Microbial Pesticide Name: Bacillus thuringiensis subsp.
OPP Chemical Code: 006402 kurstaki

Microbial Pesticide Name: Bacillus thuringiensis subsp.
OPP Chemical Code: 006403 aizawai

Microbial Pesticide Name: Bacillus thuringiensis subsp.
OPP Chemical Code: 128946 san diego

Microbial Pesticide Name: Bacillus thuringiensis subsp.
OPP Chemical Code: 006405 tenebrionis

Year of Initial Registration: 1961

Pesticide Type: Insecticide

U.S. and Foreign Producers:

Bacillus thuringiensis subsp. israelensis

- Abbott Laboratories, Chicago, IL
- Duphar B.V., Weesp, Holland
- Novo Industri AS, Copenhagen, Denmark
- Zoecon Corporation, A Sandoz Company
  Dallas, Texas

Bacillus thuringiensis subsp. kurstaki

- Abbott Laboratories, Chicago, IL
- Duphar B.V., Weesp, Holland
- Novo Industri AS, Copenhagen, Denmark
- Sandoz Crop Protection Corp.,
  Des Plaines, IL
- Ecogen, Inc., Langhorne, PA

Bacillus thuringiensis subsp. aizawai

- Sandoz Crop Protection Corp.,
  Des Plaines, IL

Bacillus thuringiensis subsp. san diego

- Mycogen Corporation, San Diego, CA

Bacillus thuringiensis subsp. tenebrionis

- Sandoz Crop Protection Corp.,
  Des Plaines, IL

2. USE PATTERNS AND FORMULATIONS

Target Pests: Bacillus thuringiensis subsp. israelensis: mosquito (larvae), fungus gnats (larvae), and black flies (larvae);
B.t. subsp. aizawai: Greater wax moth (larvae);
B.t. subsp. kurstaki: Lepidopterous larvae
B.t. subsp. san diego: Colorado potato beetle (larvae) and elm leaf beetle (larvae and adults)
B.t. subsp. tenebrionis: Colorado potato beetle

Registered Uses:

B.t. subsp. israelensis: Terrestrial food crop use on pastures;

Aquatic food crop use on rice;

Aquatic nonfood crop use on brackish water, mangrove swamps, salt marshes, tidal water, drainage systems, irrigation systems, flood water areas, woodland pools, standing water, polluted water, sewage waste lagoons, ponds, lakes, and streams;

Greenhouse nonfood crop use on ornamental plants;

Domestic outdoor use on standing water around the dwellings.

B.t. subsp. aizawai: Indoor use on empty honeycombs.

B.t. subsp. kurstaki: Terrestrial food crop uses on cotton, corn, soybeans, sorghum (grain crop), small grains, hops, fruits (banana, blueberry, caneberries, cranberry, currant, citrus fruits, grapes, kiwi fruit, pome fruits, stone fruits, small fruits, strawberry, tropical fruits, vegetables (artichoke, asparagus, avocado, beans, beets, carrots, celery, cole crops, cucumber, dandelion, eggplant, endive, lentils, lettuce, melons, okra, onions, parsley, parsnip, peas, pepper, potato, pumpkin, radish, rutabaga, safflower, spinach, squash,

sugar beets, sugar maple, sunflower, sweet potato, Swiss chard, ti, tomato, watercress, watermelon), nuts (nut crops, nut trees, peanut, walnut), flavoring and spice crops, garlic, horseradish, mint, salisfy, and forage crops, alfalfa, hayage, pastures and rangelands;

Terrestrial nonfood crop uses on tobacco, ornamental flowering and herbaceous plants, ornamental and/or shade trees, and ornamental turf;

Aquatic food crop use on rice and wild rice;

Greenhouse food crop uses on beans, beets, carrots, celery, cole crops, cucumber, eggplant, endive, flavoring and spice crops, garlic, lentils, lettuce, melons, onions, parsley, peas, peppers, potato, radish, spinach, squash, sweet potato, strawberry, tomato.

Greenhouse nonfood crop uses on agricultural research crops and ornamental flowering, herbaceous and woody plants;

Forestry uses on forest trees;

Indoor uses on stored birdseed; herbs, spices, and condiments; grain crops; peanuts; agricultural and oil seeds; soybeans, sunflower, and tobacco (including flue-cured).

B.t. subsp. san diego: Terrestrial food crop uses on eggplant, potato and tomato; Terrestrial nonfood crop uses on elm trees.

B.t. subsp. tenebrionis: Terrestrial food crop use on potatoes.

Methods of Application: Hand sprayer; water treatment by aerial or ground equipment; soil application by drip or overhead irrigation systems; foliar application by aerial, conventional ground or

hand-held equipment and
center-pivot irrigation systems;
sprayer or sprinkler cans.

Formulations: Technicals, formulation intermediate, dusts, granular, pelleted/tablet, wettable powder, emulsifiable concentrate, flowable concentrate, ready-to-use, and pressurized liquid.

3. SCIENCE FINDINGS

The Agency reviewed and evaluated available data, including both data submitted to the Agency in support of registration of B. thuringiensis as an active ingredient and data from the published literature. This information served as the basis for issuance of a draft Registration Standard in 1986. On October 10, 1986, the Agency informed the public regarding the availability of the draft Registration Standard for comment in the FEDERAL REGISTER, 51 FR 37488. In the comment period of two months, five commenters responded to the Agency. All comments have been taken into consideration in the issuance of this final Registration Standard. The specific comments, as well as the Agency's responses, are present in the public docket assigned to this Registration Standard.

In the 1986 draft Registration Standard, the Agency concluded that adequate data were available to assess the toxicological and other biological effects of B. thuringiensis on mammals, that no data gaps existed in the toxicology data base, and that there were no substantial human or environmental safety concerns except for certain endangered lepidopteran insect species. Although substantial gaps were found to exist in the ecological effects data base, there were no substantive concerns regarding unreasonable adverse effects of B. thuringiensis for the registered products. Therefore, the Agency concluded that the use of B. thuringiensis products could be continued, and that products could be used as registered, with only minor precautionary labeling changes and additional nontarget organism data being required.

Since the issuance of the 1986 draft Registration Standard, the Agency has revised the Pesticide Assessment Guidelines Subdivision M, reassessed hazard to endangered species, and has reviewed additional data on B. thuringiensis. The Agency has also more keenly focused on product identity; i.e., strain-to-strain variability within subspecies designations. Current methods applicable to strain identification have advanced considerably since the initial B. thuringiensis registration (1961). As with conventional chemical products, it is essential to know product identity so that the applicability of test results, i.e. toxicity testing and host range, can be related to specific products. A major focus of this Registration Standard is to obtain state-of-the-art identification data on B. thuringiensis strains. Each registered strain must be placed in a recognized culture collection and is subject to the data requirements of this Standard.

Although the data submitted to the Agency since 1986 show rodent and nontarget organism effects, these data do not change the assessment of the draft 1986 Registration Standard that there is no evidence of any substantial human or environmental safety concerns related to current uses of B. thuringiensis. Furthermore, there is no evidence that B. thuringiensis poses a health risk via the oral route of exposure.

The nontarget organism effects include acute toxicity in birds (178 ppm LD_{50} and 1 ppm NOEL) and suggest adverse effects in freshwater fish, plants, aquatic invertebrates, and rare beneficial insects. The contribution of inert ingredients to toxicity as well as the relevance to environmental risk of routes of exposure and dose levels used in testing have yet to be determined. Therefore, whether these results show hazard to the environment cannot be determined until additional data are submitted.

Endangered Species

Risk to federally listed endangered species cannot be fully determined at this time. However, the U.S. Fish and Wildlife Service (FWS) has determined (1987) that certain uses of the subspecies kurstaki jeopardize the continued existence of the Kern primrose sphinx moth, Lange's metalmark butterfly, Smith's blue butterfly, El Segundo blue butterfly, Oregon silverspot butterfly, San Bruno elfin butterfly, Lotis blue butterfly, and the Schaus swallowtail butterfly. An earlier consultation (1984) with FWS addressing rangeland/pastureland pesticide use found that B. thuringiensis (subspecies not specified) jeopardize the existence of the Kern Primrose Sphinx moth, Delta Green Ground Beetle, and the Valley Elderberry Longhorn Beetle. As some B. thuringiensis products have activity against dipterans, these products could effect any endangered dipterans that may be listed in the future.

Tolerances

The 40 CFR 180.1011 tolerance exemption for B. thuringiensis is currently being reevaluated by the Agency. This reevaluation will continue as data submitted in response to the Registration Standard are reviewed. Areas which the Agency wishes to address in this reevaluation include the scope of the exemption (e.g. whether asporogenic strains should be included), quality assurance measures, limits or restriction on the presence of beta-exotoxin and whether or not the mouse subcutaneous test should be replaced with a mouse intraperitoneal test.

The 40 CFR 180.1001(c) inert tolerance exemption for B. thuringiensis fermentation solids and/or solubles is also currently being reevaluated by the Agency as product analysis data are submitted in response to the Registration Standard.

4. SUMMARY OF THE REGULATORY POSITIONS

a. The Agency is requiring special tests designed to more accurately characterize strains of Bacillus thuringiensis. These data will be used to reclassify registered strains into groups of strains with similar characteristics.

b. Registrants and applicants must identify the number of B. thuringiensis strains present in their products; each strain is subject to all the data requirements applicable to the use pattern(s) of that strain.

c. Upon review of the data submitted in response to the Registration Standard, the Agency will reevaluate the current tolerance exemption for B. thuringiensis (40 CFR 180.1011) and the inert tolerance exemption for B. thuringiensis fermentation solids and/or solubles (40 CFR 180.1001 (c)).

d. Testing requirements set forth for food use products (CFR 40 180.1011) will be required for nonfood uses of B. thuringiensis as well. Analysis for production batch contaminating microorganisms and their metabolites is not currently required of nonfood use products, such as those used in forestry programs. In order to assure public and applicator safety, the Agency believes such testing requirements need to be imposed on all B. thuringiensis products.

e. The Agency is not requiring data on ground water.

f. The Agency is not requiring Endangered Species labeling at this time.

g. The Agency is not initiating a Special Review of B. thuringiensis at this time.

h. B. thuringiensis does not meet the criteria for Restricted Use at this time.

i. The Agency is not requiring a reentry interval for B. thuringiensis.

j. Protective clothing is not required for users of any B. thuringiensis products at this time.

k. Each registered strain is to be deposited in a recognized culture collection.

6. SUMMARY OF MAJOR DATA GAPS

Due to the current Agency grouping of B. thuringiensis active ingredients by subspecies and the variability of strains within a subspecies, data supporting one strain within a subspecies may not be adequate to support another strain in the same subspecies. Each distinct strain, including each strain within a subspecies (active ingredient), is subject to all the data requirements applicable to the use pattern(s) of that strain. In order to utilize data submitted to the Agency prior to the issuance of the Registration Standard, registrants must show that the strain used in testing is substantially similar to the strain present in the product currently. Data gaps exist for all

requirements listed in the data tables of the Registration Standard. However, some of these gaps may be filled if the registrant shows that the strain used in testing is substantially similar to the strain present in the product currently.

7. CONTACT PERSON AT EPA

Phillip O. Hutton
Product Manager (17)
Insecticide Rodenticide Branch
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
401 M Street, S. W.
Washington, D. C. 20460

Office location and telephone number:

Room 207, Crystal Mall #2
1921 Jefferson Davis Highway
Arlington, VA 22202
(703) 557-2690

DISCLAIMER: The information in this Pesticide Fact Sheet is a summary only and is not to be used to satisfy data requirements for pesticide registration and reregistration. The complete Registration Standard for the pesticide may be obtained from the National Technical Information Service. Contact the Product Manager listed above for further information.